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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,493	06/05/2001	Ronny van't Oever	6811.US.O1	6161

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EXAMINER

HESS, DANIEL A

ART UNIT PAPER NUMBER

2876

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,493

Applicant(s)

OEVER ET AL.

Examiner

Daniel A Hess

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12 and 21 is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Receipt is acknowledged of amendment filed 11/19/2002, which has been placed in the file of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 13-15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tycko (US 5,194,909) in view of Altendorf (US 6,067,157).

Tycko shows (column 7, line 66; column 4, lines 65-70) the spherizing of red blood samples using spherizing reagent. The solution is (column 8, lines 8-15) a neutrally buffered saline solution (7.4 pH). Individual cells are 'entrained' (column 5, line 4). There is a 'stream'

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(column 15, line 51) of liquid containing the cells. Light of a particular color is shone on the cells (column 5, line 9; column 9, line 41). Tycko further shows that scattering measurements are taken at two particular angles (figures 4 and 5). Although he doesn't show explicitly how the angular differentiation is achieved, it is clear he must have a way. Intensities for scattering within these angles is obtained (figures 3 and 4). Tycko shows a means for determining volume and hemoglobin concentration on a cell-by-cell basis: Tycko does show the use of plots to correlate the three variables of volume (V), HC and a scatter signal in figures 4 and 5, although he only shows this in two dimensions.

Tycko fails to show additional analysis as claimed for white blood cells.

Altendorf (see column 1-3) uses the same data as Tycko collects to analyze shape, size, etc of white blood cells.

Re claims 14 and 15: Tycko shows in figures 3 that scattering is obtained for a range of angles, which includes front, intermediate, and side. These are used to obtain hemoglobin concentration and blood volume.

Re claim 19: Tycko's wavelength of 632 nm (column 6, line 51) falls within this range.

Re claim 20: Clearly Tycko had a HeNe laser in mind when he named a 632 nm light source.

5. Claim 16 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Tycko as modified by Altendorf as applied to claim 13 above, and further in view of Rodriguez et al. (US 5,616,501).

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Tycko as modified by Altendorf fails to show the explicit separation of reticulocytes using dye to find maturity.

Rodriguez shows (column 15, claims 1 and 2) the use of fluorescent dye (claim 1, c) to find cell maturity (claim 2).

In view of Rodriguez' teachings, it would have been obvious at the time the invention was made to employ fluorescent dye techniques to measure cell maturity because one would want to factor out the effect of immature cells when analyzing data.

6. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tycko as modified by Altendorf as applied to claim 13 above, and further in view of Kirchanski et al. (US 4,882,284).

Tycko as modified by Kim, as discussed above, could include measurement of any of ALL, IAS, FL3, PSS, and DSS.

Tycko as modified by Kim fails to show determination of internal cell complexity and granularity.

Kirchanski shows (column 6, lines 40-50) that internal cell structure and granularity can be determined for white cells using scattering data.

In view of Kirchanski's teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the old and well-known use of scattering data to determine internal cell complexity and granularity as taught by Kirchanski in the teachings of Tycko as modified by Kirchanski because these determinations can aid in the diagnosis of blood ailments.

Allowable Subject Matter

7. Claims 1-12 and 21 are allowed.

The nearest available prior art of record, Tycko (US 5,194,909), shows (column 7, line 66; column 4, lines 65-70) the spherizing of red blood samples using spherizing reagent. The solution is (column 8, lines 8-15) a neutrally buffered saline solution (7.4 pH). Individual cells are 'entrained' (column 5, line 4). There is a 'stream' (column 15, line 51) of liquid containing the cells. Light of a particular color is shone on the cells (column 5, line 9; column 9, line 41). Tycko further shows that scattering measurements are taken at two particular angles (figures 4 and 5). These are 'forward scattering' measurements (column 5, lines 10-12). Tycko does show the use of plots to correlate the three variables of volume (V), HC and a scatter signal in figures 4 and 5, although he only shows this in two dimensions. However, in doing so, Tycko illustrates the principle of using gridded lines in a third variable to include 3 variables in 2 dimensions. Tycko also shows that a given measurement of scattering at a certain angle forms a single 'equation' for the variables of volume V and hemoglobin concentration HC (see figures 4 and 5). In figures 4 and 5, Tycko effectively shows two such equations.

Tycko notably fails to teach or suggest "projecting a three-dimensional coordinate of light scatter signals from each cell onto a three-dimensional surface containing grid lines of V and HC."

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Nowhere else does the prior art of record teach or suggest the 3-dimensional analytical techniques claimed by the applicant for using a variety of scatter signals to obtain measurements of hemoglobin concentration and blood volume.

Remarks

8. Examiner recognizes that the earlier rejection under 35 USC 103 of the various claims using a reference that was commonly owned with the applicant falls in light of proof of this common ownership.

Since the grounds given for rejection of claims 13-20 are new, this action is therefore not made final.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel A Hess whose telephone number is (703) 305-3841. The examiner can normally be reached on 8:00 AM - 5:00 PM M-F.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Lee can be reached on (703) 305-3503. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

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A handwritten signature in black ink, appearing to be 'DAH'.

DH

December 30, 2002

Daniel A Hess

Examiner

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A handwritten signature in black ink, appearing to be 'Karl D. Frech'.

KARL D. FRECH
PRIMARY EXAMINER